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| CHIEF INTELLECTUAL PATENT COUNSEL AFFYMETRIX, INC. 3380 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051 | | | EXAMINER BEISNER, WILLIAM H | |
| | | | ART UNIT 1744 | PAPER NUMBER |

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/927,431 | MATHIES ET AL. | |
| | Examiner | Art Unit | |
| | William H. Beisner | 1744 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-13 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 01 February 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5&6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 19 March 2002 and 22 March 2002 have been considered and made of record. Note the references that have been lined through on the Form PTO-1449 dated 19 March 2002 are duplicates of those listed on Form PTO-1449 dated 22 March 2002.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5 and 6, "said cavity" lacks antecedent basis. These claims depend from claims 1 which recites "a reaction chamber". It is not clear from the current claim language if the reaction chamber and the cavity are the same structures. Clarification and/or correction is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Zanzucchi et al.(US 5,593,838).

With respect to claim 1, the reference of Zanzucchi et al. discloses a miniature reaction chamber including a body (14) with a reaction chamber or cavity (36), a resistive heater (57) deposited within the cavity, a temperature sensor (59) for determining a temperature within the cavity. Both the heater and sensor being connected to computer controlled power supply (10).

With respect to claim 2, the device includes a second reaction chamber (40) fluidly connected to reaction chamber (36).

With respect to claim 5, the cavity is formed by planar members (14) and (63).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al.(US 5,593,838).

The reference of Zanzucchi et al. has been discussed above.

With respect to the claimed volumes of the cavity recited in claims 7-9, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

10. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al.(US 5,593,838) in view of Harkins (US 3,901,437).

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The reference of Zanzucchi et al. has been discussed above.

With respect to claim 10, while the reference of Zanzucchi et al. discloses the use of a thermocouple to sense the temperature with the reaction chamber, the reference is silent as to the use of a reference junction that is located external to the reaction chamber.

The reference of Harkins discloses that it is known in the art to provide a reference junction with a thermocouple device that is positioned so as to be exposed to the ambient temperature that is external to the environment of the sensing junction (See column 4, lines 16-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a reference junction that is external to the reaction chamber for the known and expected result of providing a means recognized in the art for compensating for variations in ambient temperature.

With respect to claim 11, while the reference of Zanzucchi et al. discloses the use of a thermocouple, the reference is silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device of the primary reference for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

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11. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al.(US 5,593,838) in view of Northrup et al.(WO 94/05414) alone or alternatively further in view of Stix (Scientific American).

The reference of Zanzucchi et al. has been discussed above.

The above claims further differ by reciting that the device further includes detection means that include a plurality of microcapillaries or an oligonucleotide array.

The reference of Northrup et al. discloses that it is conventional in the art to employ microelectrophoresis (See pages 4 and 10) or two-dimensional arrays (See pages 13 and 14) to detect or verify PCR products. Microfabricated devices to perform the detection procedures discussed by Northrup et al. are conventional in the art.

As a result, it would have been obvious to one of ordinary skill in the art to employ any of the well-known means in the art to detect the post-PCR products produced by the system of the primary reference. Use of microelectrophoresis or arrays of oligonucleotides would have been obvious for the known and expected result of employing an alternative means recognized in the art to achieve the same result, detection of post-PCR products.

Additionally, if the disclosure of Northrup et al. is considered to be insufficient to meet the claim limitations, the reference of Stix discloses that it is conventional in the art to link several of the well known "chip" devices so that post-PCR products are detected or verified.

As a result, it would have been obvious to one of ordinary skill in the art to link several of the well known "chip" devices (microelectrophoresis or oligonucleotide arrays) together for the known and expected result of detecting post-PCR products as is suggested by both of the references of Northrup et al. and Stix.

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12. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al.(US 5,593,838) in view of Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276).

The reference of Zanzucchi et al. has been discussed above.

The claims further differ by specifying that the materials of construction of the heating device and the thermocouple device.

The reference of Zdeblick discloses a microdevice which includes a heating device (20) which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to determine the optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

To further support the obviousness of the materials of construction, the reference of Loux et al. is cited as disclosing a microdevice which includes a resistive heating device which includes a trace (11) which is made of chromium and is connected to gold pads (14 and 15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ chromium and gold as materials for the temperature control system of the modified primary reference for the known and expected result of using materials which can be used in microdevices.

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13. Claims 1-5, 7-9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stix (Scientific American) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276).

The reference of Stix discloses a miniature reaction chamber which includes a heater (See the Figure).

While the reference discloses the use of a heater device within the microchamber, the reference is silent as to the use of a resistive heater temperature control system used to control or cycle the heater within the microchamber.

The reference of Garner discloses that it is well known in the art to provide a resistance heater device within a PCR or thermocycling device with a temperature sensor (thermocouple) and an appropriately programmed computer for monitoring the temperature and operating a power source to control the heater device.

The reference of Zdeblick discloses a microdevice which includes a heating device (20) which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the reference of Stix for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules. With respect to the construction of the heater and thermocouple recited in claims 12 and 13, it would have been obvious to one of ordinary skill in

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the art to determine the optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

To further support the obviousness of the materials of construction, the reference of Loux et al. is cited as disclosing a microdevice which includes a resistive heating device which includes a trace (11) which is made of chromium and is connected to gold pads (14 and 15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ chromium and gold as materials for the temperature control system of the modified primary reference for the known and expected result of using materials which can be used in microdevices.

With respect to the claimed microcapillaries and oligonucleotide arrays of claims 3 and 4, the reference of Stix discloses that it is conventional in the art to link several of the well known "chip" devices so that post-PCR products are detected or verified.

As a result, it would have been obvious to one of ordinary skill in the art to link several of the well known "chip" devices (microelectrophoresis or oligonucleotide arrays) together for the known and expected result of detecting post-PCR products as is suggested by both of the references of Northrup et al. and Stix.

With respect to the claimed volumes of the cavity recited in claims 7-9, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

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14. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stix (Scientific American) in view of Garner (US 5, 241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276) taken further in view of Harkins (US 3,901,437).

The combination of the references of Stix with Garner and Zdeblick alone or further in view of Loux et al. has been discussed above.

With respect to claim 10, while the modified primary reference suggests the use of a thermocouple to sense the temperature with the reaction chamber, the reference is silent as to the use of a reference junction that is located external to the reaction chamber.

The reference of Harkins discloses that it is known in the art to provide a reference junction with a thermocouple device that is positioned so as to be exposed to the ambient temperature that is external to the environment of the sensing junction (See column 4, lines 16-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a reference junction that is external to the reaction chamber for the known and expected result of providing a means recognized in the art for compensating for variations in ambient temperature.

With respect to claim 11, while the modified primary reference suggests the use of a thermocouple, the reference is silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device of the primary reference for the

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known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

15. Claims 1-5, 7-9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.(WO 94/05414) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276).

The reference of Northrup et al. discloses a miniature reaction device which includes at least one reaction chamber defined within a body. The reference discloses the use of heaters (See page 2, 3, 9), a plurality of chambers within the same body (See Figure 2), electrophoretic detection means (See page 20), probe arrays (See pages 13 and 14), and lamb wave pumps and/or mixers (See page 9).

While the reference discusses the use of microheaters which include resistive heaters made as an integral part of the microstructure, the reference is silent as to the specifics of the temperature control of the microheating device. Specifically, independent claim 1 requires the use of a temperature sensor provided within the cavity and a programmed computer connected to the heater and sensor.

The reference of Garner discloses that it is well known in the art to provide a resistance heater device within a PCR or thermocycling device with a temperature sensor (thermocouple) and an appropriately programmed computer for monitoring the temperature and operating a power source to control the heater device.

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The reference of Zdeblick discloses a microdevice which includes a heating device, 20, which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the reference the modified primary reference for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules. Additionally with respect to the materials of the heater and thermocouple recited in claims 12 and 13, it would have been obvious to one of ordinary skill in the art to determine the optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

To further support the obviousness of the materials of construction, the reference of Loux et al. is cited as disclosing a microdevice which includes a resistive heating device which includes a trace, 11, which is made of chromium and is connected to gold pads, 14 and 15.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ chromium and gold as materials for the temperature control system of the modified primary reference for the known and expected result of using materials which can be used in microdevices.

With respect to the claimed volumes of the cavity recited in claims 7-9, while the reference does not specifically recite the volume of the disclosed cavities, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on

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design considerations such as the specific method or assay which is intended to be performed within the device.

With respect to claims 2-4, see pages 13, 14 and 20 of Northrup et al. which disclose the use of electrophoresis detection and probe arrays.

16. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.(WO 94/05414) in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) alone or in combination with Loux et al.(US 5,544,276) taken further in view of Harkins (US 3,901,437).

The combination of the references of Northrup et al. with Garner and Zdeblick alone or further in view of Loux et al. has been discussed above.

With respect to claim 10, while the modified primary reference suggests the use of a thermocouple to sense the temperature with the reaction chamber, the reference is silent as to the use of a reference junction that is located external to the reaction chamber.

The reference of Harkins discloses that it is known in the art to provide a reference junction with a thermocouple device that is positioned so as to be exposed to the ambient temperature that is external to the environment of the sensing junction (See column 4, lines 16-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a reference junction that is external to the reaction chamber for the known and expected result of providing a means recognized in the art for compensating for variations in ambient temperature.

With respect to claim 11, while the modified primary reference suggests the use of a thermocouple, the reference is silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device of the primary reference for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

Double Patenting

17. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

18. Claim 6 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 28 of prior U.S. Patent No. 6,132,580. This is a double patenting rejection.

19. Claim 6 is directed to the same invention as that of claim 28 of commonly assigned U.S. Patent No. 6,132,580. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,284,525 in view of Northrup et al.(wo 94/05414) or Zanzucchi et al.(US 5,593,838). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of

U.S. Patent No. 6,284,525 encompasses substantially the same device, the instant claims recite a "resistive heater" while the patented claims merely recite a "heater".

The references of Northrup et al. (See page 9, lines 29-32) and Zanzucchi et al. (See Figure 4B) both disclose that the use of resistive heaters are known in the art for heating the contents of a reaction chamber in a microfluidic device.

As a result, it would have been obvious to one of ordinary skill in the art to employ a resistive heater in the system encompassed by the patented claims for the known and expected result of providing a heater device recognized in the art for heating and/or controlling the temperature within a microfluidic reaction chamber.

With respect to claim 2, see patented claims 1, 8, 10 and 11.

With respect to claim 3, see patented claims 1, 8, and 10.

With respect to claim 4, see patented claim 11.

With respect to claim 5, see patented claim 12.

With respect to claim 6, see patented claims 7 and 9.

With respect to claims 7-9, see patented claims 13-15.

With respect to claim 10, see patented claim 16.

With respect to claim 11, see patented claim 17.

With respect to claim 12, see patented claim 18.

With respect to claim 13, see patented claim 19.

22. Claims 1-5 and 7-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,132,580 in

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view of Northrup et al.(wo 94/05414) or Zanzucchi et al.(US 5,593,838). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,132,580 encompasses substantially the same device, the instant claims recite a “resistive heater” while the patented claims merely recite a “heater”.

The references of Northrup et al. (See page 9, lines 29-32) and Zanzucchi et al.(See Figure 4B) both disclose that the use of resistive heaters are known in the art for heating the contents of a reaction chamber in a microfluidic device.

As a result, it would have been obvious to one of ordinary skill in the art to employ a resistive heater in the system encompassed by the patented claims for the known and expected result of providing a heater device recognized in the art for heating and/or controlling the temperature within a microfluidic reaction chamber.

With respect to claim 2, see patented claims 1 and 2.

With respect to claim 3, see patented claim 1.

With respect to claim 4, see patented claim 2.

With respect to claim 5, see patented claim 3.

With respect to claims 7-9, see patented claims 9-11.

With respect to claim 10, see patented claim 12.

With respect to claim 11, see patented claim 13.

With respect to claim 12, see patented claim 14.

With respect to claim 13, see patented claim 16.

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23. Claims 1-9 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,261,431. Although the conflicting claims are not identical, they are not patentably distinct from each other because the combination of a heater that is a resistive heater and the use of a computer to monitor and control a power source for the heater recited in claim 1 of the instant claims is not included as a combination of elements in a single claim of the patented claims. However, patented claim 6 discloses the use of a resistive heater and patented claim 17 discloses the use of a controller for controlling the temperature of the reactions chamber. As a result, it would have been obvious to one of ordinary skill in the art to employ both the resistive heater and controller as suggested by the claimed to define a device that is the same as that required of instant claim 1.

With respect to claim 2, see patented claims 1 and 14.

With respect to claim 3, see patented claim 1.

With respect to claim 4, see patented claim 14.

With respect to claim 5, see patented claim 1.

With respect to claim 6, see patented claim 10.

With respect to claims 7-9, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

With respect to claim 12, see patented claim 16.

24. Claims 10 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,261,431 in view of

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Harkins (US 3,901,437). The device encompassed by claims 1-17 of U.S. Patent No. 6,261,431 has been discussed above.

With respect to claim 10, while the patented claims suggest the use of a thermocouple to sense the temperature with the reaction chamber, the patented claims are silent as to the use of a reference junction that is located external to the reaction chamber.

The reference of Harkins discloses that it is known in the art to provide a reference junction with a thermocouple device that is positioned so as to be exposed to the ambient temperature that is external to the environment of the sensing junction (See column 4, lines 16-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system encompassed by the patented claims with a reference junction that is external to the reaction chamber for the known and expected result of providing a means recognized in the art for compensating for variations in ambient temperature.

With respect to claim 11, while the patented claims suggest the use of a thermocouple, the reference is silent as to the use of a DC voltage with the thermocouple.

The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device encompassed by the patented claims for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

25. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,261,431 in view of Zdeblick (US 4,821,997). The device encompassed by claims 1-17 of U.S. Patent No. 6,261,431 has been discussed above.

With respect to claim 13, while the patented claims suggest the use of a thin film resistive heater, they do not disclose the use of a chromium film with gold leads.

The reference of Zdeblick discloses a microdevice which includes a heating device, 20, which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the device encompassed by the patented claims for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules. Additionally with respect to the materials of the heater 13, it would have been obvious to one of ordinary skill in the art to determine the optimum manner and material in which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

26. Claims 1-9 and 11-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-20 of copending Application No. 09/906,411 in view of Garner (US 5, 241,363) and Zdeblick (US 4,821,997).

Claims 1-3 and 5-20 of application '411 encompass a device that is substantially the same as that recited in claims 1-9, 12 and 13 of the instant application.

While the claims of application '411 encompass the use of microheaters which include resistive heaters made as an integral part of the microstructure, the reference is silent as to the specifics of the temperature control of the microheating device. Specifically, independent claim 1 requires the use of a temperature sensor provided within the cavity and a programmed computer connected to the heater and sensor.

The reference of Garner discloses that it is well known in the art to provide a resistance heater device within a PCR or thermocycling device with a temperature sensor (thermocouple) and an appropriately programmed computer for monitoring the temperature and operating a power source to control the heater device.

The reference of Zdeblick discloses a microdevice which includes a heating device, 20, which can include a thermocouple device (See Column 8, lines 32-39). The reference also discloses a number of materials which can be used to construct the elements of the microdevice.

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide a heater and control system as disclosed by the references of Garner and Zdeblick in combination with the device encompassed by the claims of application '411 for the known and expected result of providing a means recognized in the art for controlling the temperature within a reaction chamber which is used to synthesize biochemical molecules. Additionally with respect to the materials of the heater and thermocouple recited in claims 12 and 13, it would have been obvious to one of ordinary skill in the art to determine the optimum manner and material in

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which to construct the resistive heater device and associated thermocouple device while maintaining the required temperature control.

With respect to claim 2, see claims 1, 5 and 15 of application '411.

With respect to claim 3, see claims 1 and 5 of application '411.

With respect to claim 4, see claim 15 of application '411.

With respect to claim 5, see claims 16 of application '411.

With respect to claim 6, see claim 17 of application '411.

With respect to claims 7-9, it would have been obvious to one of ordinary skill in the art to optimize the volume of the cavities based merely on design considerations such as the specific method or assay which is intended to be performed within the device.

With respect to claim 10, see claim 18 of application '411.

With respect to claim 12, see claim 19 of application '411.

This is a provisional obviousness-type double patenting rejection.

27. Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-20 of copending Application No. 09/906,411 in view of Garner (US 5,241,363) and Zdeblick (US 4,821,997) taken further in view of Harkins (US 3,901,437).

The combination of claims 1-3 and 5-20 of copending application '411 with Garner and Zdeblick has been discussed above.

With respect to claim 11, while claims encompassed by application '411 suggest the use of a thermocouple, these claims are silent as to the use of a DC voltage with the thermocouple.

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The reference of Harkins discloses that it is conventional in the art to measure a DC voltage across the thermocouple-sensing device (See column 4, lines 35-54).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to measure DC voltage across the thermocouple of the device encompassed by the claims of application '411 for the known and expected result of using the measured voltage to determine the temperature within the reaction chamber.

This is a provisional obviousness-type double patenting rejection.

28. Claims 1-13 are directed to an invention not patentably distinct from claims 1-36 of commonly assigned Patent No. 6,284,525. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the obviousness-type double patenting rejection above.

29. Claims 1-5 and 7-13 are directed to an invention not patentably distinct from claims 1-27 of commonly assigned Patent No. 6,132,580. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the obviousness-type double patenting rejection above.

30. Claims 1-13 are directed to an invention not patentably distinct from claims 1-17 of commonly assigned Patent No. 6,261,431. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the obviousness-type double patenting rejections above.

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31. Claims 1-13 are directed to an invention not patentably distinct from claims 1-3 and 5-20 of commonly assigned application 09/906,411. Specifically, the claims are not patentably distinct for the same reasons as set forth above with respect to the provisional obviousness-type double patenting rejections above.

32. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent Nos. 6,132,580 and 6,284,525, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

33. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Fujita et al.(JP 05-317030) is cited as prior art that depicts a cavity with a heating means in the cavity.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB